# 510(K) SUMMARY

[as required by section 807.92(c)]

## EC Single Use, Polypectomy Snare

JAN 10 2013

**510(k) Number K** 123223

**Date Prepared:**
October 10, 2012

**Applicant's Name:**
EndoChoice, Inc.
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**Contact Person:**
Shoshana (Shosh) Friedman
Regulatory Consultant
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**Trade Name:**
EC Single Use, Polypectomy Snare

**Classification Name:**
Flexible Snare

**Classification:**
FDA has classified Flexible Snare devices for as class II devices (product code FDI) and they are reviewed by the Gastroenterology/Urology.

**Predicate Devices:**
Olympus SD Series Snares – K955650

**Device Description:**
The EC Single Use, Polypectomy Snare is a disposable sterile device comprised of a snare loop, a snare tube, a mandrel, a slider and a plug. An electrical connection enables the snare loop to be connected to an electrosurgical generator. Tissue is resected by a combination of mechanical handling of the loop and electrosurgical current.

**Intended Use:**
The EC Single Use, Polypectomy Snare is indicated to endoscopically resect tissue from within the GI tract.

**Technological Characteristics:**

The technological characteristics of the EC Single Use, Polypectomy Snare are virtually identical to those of the Olympus SD Series Snares cleared under K955650.

**Performance Testing:**

Results of the various tests indicate that the EC Single Use, Polypectomy Snare functions as intended.

**Conclusion:**

EndoChoice Inc. believes that, based on the information provided in this submission, EC Single Use, Polypectomy Snare is substantially equivalent to its predicate device without raising any new safety and/or effectiveness issue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 10, 2013

EndoChoice, Inc.
% Ms. Shoshana Friedman
Regulatory Consultant
Push-Med LLC
1914 J.N. Pease Place
CHARLOTTE NC 28262

Re: K123223
Trade/Device Name: EC Single Use, Polypectomy Snare
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: FDI
Dated: December 10, 2012
Received: December 11, 2012

Dear Ms. Friedman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**INDICATIONS FOR USE STATEMENT**

**510(k) Number (if known):** K123223

**Device Name:** EC Single Use, Polypectomy Snare

**Indications for Use:**

The EC Single Use, Polypectomy Snare is indicated to endoscopically resect tissue from within the GI tract.

Prescription Use _X_ (Per 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123223